

## ***Remarks***

### ***I. The Claims***

Upon entry of the foregoing amendments, claims 1, 5-8, 11-14, 16-19 and 21 are pending in the application, with claim 1 being the sole independent claim. Claim 11 is sought to be amended. Claims 9, 10 and 15 are sought to be cancelled. No new matter is added by way of these amendments. It is respectfully requested that the amendments be entered and considered.

### ***II. Withdrawn Rejections***

Applicants appreciate and acknowledge that the Examiner has withdrawn the rejections of claims 1-4, 6, 7, and 16-23 under 35 U.S.C § 112, first paragraph. (Office Action, page 2.)

Applicants appreciate and acknowledge that the Examiner has withdrawn the rejections of claims 13-15 as provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 157-161, 163-170, 172, 174, 183, 196-219 and 230-232 of U.S. Patent Application 09/958,809. (Office Action, page 2.)

### ***III. CLAIMS ARE NOT ANTICIPATED***

#### ***A. Pecora et al. does not anticipate the present claims***

“Claims 1, 5-8, 13, 14, 16-19 and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Pecora et al. (Journal of Clinical Oncology, 2002, 20(9):2251-2266) as evidenced by Laurie et al. (Clin. Cancer Res., 2006, 12(8):2555-2562), Chandler et al. (American Journal of Surgery, 1965, 109:221-222), Martensson et al. (Journal of Surgical Oncology, 1984, 27:152-158), Drougas et al. (Am. J Surg., 1998,175:408-412) and Wessels et al. (Journal of Surgical Research, 2001, 95, 8-12).” (Office Action, page 3.) Applicants respectfully disagree.

To anticipate a patent claim a prior art reference must disclose, either expressly or inherently, all of the limitations of the claim. “Inherency, however, may not be established by probabilities or possibilities.” (*Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991), quoting *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981).)

The Examiner states, "Pecora *et al.* contemplates treating subjects with carcinoid tumors" and further states, "to reduce the size of or eliminate the tumors will inherently reduce or treat carcinoid syndrome symptoms in those subjects who have carcinoid syndrome". (Office Action, page 4, underlining added.) However, Pecora *et al.* reports the details of a clinical trial.. For Pecora *et al.* to inherently anticipate the rejected claims, the disclosure of Pecora *et al.* would had to have necessarily resulted, *inter alia*, in the decrease of one or more symptoms of carcinoid syndrome.

Pecora *et al.* does disclose that one patient had a carcinoid tumor. However, as evidenced by the Lorence Declaration, submitted herewith, the sole patient reported in Pecora *et al.* as having a carcinoid tumor did not have carcinoid syndrome. Therefore, Pecora *et al.* does not expressly or inherently disclose decreasing one or more symptoms of the carcinoid syndrome as required by the present claims.

Since Pecora *et al.* does not teach expressly or inherently all of the elements of the claims, Pecora *et al.* cannot anticipate claims 1, 5-8, 13, 14, 16-19 or 21.

***B. Roberts et al. does not anticipate the present claims***

"Claims 1, 5-8, 11-14, 16-19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Roberts *et al.* (WO 00/62735) as evidenced by Chandler *et al.* (American Journal of Surgery, 1965, 109:221-222), Martensson *et al.* (Journal of Surgical Oncology, 1984, 27:152-158), Drougas *et al.* (Am. J Surg., 1998,175:408-412) and Wessels *et al.* (Journal of Surgical Research, 2001, 95, 8-12)." (Office Action, page 5.) Applicants respectfully disagree.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (*Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).) "The identical invention must be shown in as complete detail as is contained in the ... claim." (*Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).)

The rejection states, *inter alia*,

Roberts et al. contemplates treating subjects with carcinoid tumors. This includes those subjects who also have carcinoid syndrome (It is well known in the art that patients with carcinoid syndrome have carcinoid tumors). By treating a population of subjects with carcinoid tumors with NDV, Roberts et al. will also treat the 10% or more of the subjects who also have carcinoid syndrome. Therefore, a person of ordinary skill in the art would recognize that treating carcinoid tumors with NDV, according to the method of Roberts et al., to reduce the size of or eliminate the tumors will inherently reduce or treat carcinoid syndrome symptoms in those subjects who have carcinoid syndrome as evidenced by Chandler et al. (resection of carcinoid tumors relieved carcinoid syndrome symptoms), Martensson et al. (embolization of hepatic carcinoid tumors relieved carcinoid syndrome symptoms), Drougas et al. (hepatic artery chemoembolization of carcinoid tumors relieved carcinoid syndrome symptoms) and Wessels et al. (radiofrequency ablation of carcinoid tumors relieved carcinoid syndrome symptoms).

(Office Action, pages 6-7.)<sup>1</sup>

This rejection on the grounds of alleged inherent anticipation might be well taken if carcinoid tumors always caused carcinoid syndrome. The Examiner states that “[i]t is well known in the art that patients with carcinoid syndrome have carcinoid tumors.” (Office Action, page 6.) However, as conceded by the Examiner (Office Action, page 6.) the majority of carcinoid tumors do not cause carcinoid syndrome.

The law regarding anticipation by inherency is well settled. Inherency cannot be established by mere possibilities or probabilities. (*Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991), quoting *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981).) The mere fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic, *e.g.*, see MPEP 2112(IV); *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993); and *In re Oelrich*, 666 F.2d 578, 581-82 (C.C.P.A. 1981 ). Additionally, “[o]ccasional results are not inherent.” (*Mehl/Biophile International Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999).)

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<sup>1</sup> Applicants are unsure of the source for the Examiner’s statement related to “the 10% or more of the subjects [with carcinoid tumors] who also have carcinoid syndrome.” (underlining added.) Applicants’ Reply of April 8, 2007 referred to McCormick (Gastroenterology Nursing (2001) 25(3):105-111) which states that “[l]ess than 10% of patients with carcinoids develop this syndrome.” (underlining added.)

Therefore, since carcinoid syndrome is found in only a subset of carcinoid tumor patients, the treatment of carcinoid syndrome is not inherent in the teaching of Roberts *et al.* Even if one were to assume (solely for the sake of argument) that the teachings of Roberts *et al.* may result in the treatment of a carcinoid tumor in a patient suffering from carcinoid syndrome, wherein the one or more symptoms of the carcinoid syndrome are decreased, this is not sufficient to establish inherency. Consequently, the references do not disclose every element of the claims. Accordingly, the rejection over Roberts *et al.* for alleged anticipation is improper and should be withdrawn.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1, 5-8, 11-14, 16-19 and 21 are rejected under 35 U.S.C. § 102(b).

#### ***IV. CLAIMS ARE NOT OBVIOUS***

“Claims 9, 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pecora *et al.* or Roberts *et al.*” (Office Action, page 8.) Applicants respectfully disagree.

However, solely to advance prosecution, and not in acquiescence to the Examiner’s rejection, Applicants have cancelled claims 9, 10 and 15, thus rendering moot the rejection under 35 U.S.C. § 103(a).

#### ***V. ALLEGED DOUBLE PATENTING***

Claims 1, 5-8 and 16-17 have been provisionally rejected for alleged obviousness-type double patenting over claims 1-3, 6, 7, 19, 22-25 and 27 of U.S. Patent No. 7,056,689 in view of Pecora *et al.* (Journal of Clinical Oncology, 2002, 20(9):2251-2266) and as evidenced by Chandler *et al.* (American Journal of Surgery, 1965, 109:221-222), Martensson *et al.* (Journal of Surgical Oncology, 1984, 27:152-158), Drougas *et al.* (Am. J Surg., 1998,175:408-412) and Wessels *et al.* (Journal of Surgical Research, 2001, 95, 8-12). (Office Action, page 10.)

Claims 1-8, 13, 16 and 17 have been provisionally rejected for alleged obviousness-type double patenting over claims 1-3, 6-8, 50, 51, 63-65, 69, 70, 73, 115-120, 132, 134, 136 and 144 of copending Application No. 10/167,652. (Office Action, page 12.)

Claims 13-15 have been provisionally rejected for alleged obviousness-type double patenting over claims 1-6, 12, 17, 21, 22, 26-28 and 34 of copending Application No. 10/518,732. (Office Action, page 14.)

Claims 1, 5-8 and 16-18 have been provisionally rejected for alleged obviousness-type double patenting over claims 14, 17, 18, 21, 22, 33, 34, 36-39 and 41 of copending Application No. 11/441,201. (Office Action, page 21.)

Applicants do not concede the merits of the preceding double patenting rejections. However, Applicants will consider filing a Terminal Disclaimer upon indication of otherwise allowable subject matter.

Claims 13-15 have been provisionally rejected for alleged obviousness-type double patenting over claims 1-13 of copending Application No. 10/547,654 ("the '654 application") in view of Pecora et al. (Journal of Clinical Oncology, 2002, 20(9):2251-2266) and as evidenced by Chandler et al. (American Journal of Surgery, 1965, 109:221-222), Martensson et al. (Journal of Surgical Oncology, 1984, 27:152-158), Drougas et al. (Am. J Surg., 1998, 175:408-412) and Wessels et al. (Journal of Surgical Research, 2001, 95, 8-12). (Office Action, page 15.) Applicants respectfully disagree.

Claims 13-15 have been provisionally rejected for alleged obviousness-type double patenting over claims 1-17 of copending Application No. 10/548,057 ("the '057 application") in view of Pecora et al. (Journal of Clinical Oncology, 2002, 20(9):2251-2266) and as evidenced by Chandler et al. (American Journal of Surgery, 1965, 109:221-222), Martensson et al. (Journal of Surgical Oncology, 1984, 27:152-158), Drougas et al. (Am. J Surg., 1998, 175:408-412) and Wessels et al. (Journal of Surgical Research, 2001, 95, 8-12). (Office Action, page 18.) Applicants respectfully disagree.

The '654 application and the '057 application were filed after the subject application. Accordingly, upon an indication of otherwise allowable subject matter these provisional obviousness-type double patenting rejections should be withdrawn and the subject application should be allowed to issue as a patent without a terminal disclaimer. (MPEP § 804(I)(B)(1), Rev. 5, Aug. 2006, page 800-17, right column.)

In view of the above, Applicants respectfully request the Examiner reconsider and withdraw the obviousness-type double patenting rejections.

### ***Conclusion***

It is not believed that extensions of time are required beyond those that may otherwise be provided for herein or in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, The United States Patent and Trademark Office is hereby authorized to charge any fee deficiency required to prevent abandonment of the current application or credit any overpayment to Deposit Account 50-1677.

Applicants believe that a full and complete Reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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